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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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IN RE: :  
FOSAMAX PRODUCTS LIABILITY LITIGATION :  
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This document relates to: :  
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Sylvia Clarke and Kenny Clarke v. :  
Merck, Sharpe & Dohme Corp., et al., :  
No. 12 Civ. 7167 (JFK) :  
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Theresa Marcone v. :  
Merck, Sharpe & Dohme Corp., et al., :  
No. 11 Civ. 5174 (JFK) :  
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Victoria Miller v. :  
Merck, Sharpe & Dohme Corp., et al., :  
No. 11 Civ. 5393 (JFK) :  
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Essie Small v. :  
Merck, Sharpe & Dohme Corp., et al., :  
No. 11 Civ. 5152 (JFK) :  
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Raymond Smith v. :  
Merck, Sharpe & Dohme Corp., et al., :  
No. 11 Civ. 5178 (JFK) :  
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Master File  
No. 06 MD 1789 (JFK)  
**OPINION & ORDER**

APPEARANCES

FOR PLAINTIFFS:

Brandon Bogle  
LEVIN, PAPANTONIO, THOMAS, MITCHELL, RAFFERTY & PROCTOR, P.A.

FOR TEVA PHARMACEUTICALS USA, INC.:

Carla Rose Karp  
GOODWIN PROCTER, LLP

**JOHN F. KEENAN, United States District Judge:**

Defendant Teva Pharmaceuticals USA, Inc. has moved in the  
above-captioned cases for a more definite statement pursuant to  
Rule 12(e) of the Federal Rules of Civil Procedure. For the

reasons that follow, the motion is granted in part and denied in part.

### **I. Background**

This MDL involves claims that the drug Fosamax or its generic equivalent, alendronate sodium, caused users to suffer from a condition known as osteonecrosis of the jaw ("ONJ"). Plaintiffs have asserted claims against Merck, the maker of Fosamax, and against various manufacturers of the generic alendronate sodium (the "Generic Defendants").

Generic Defendants have previously moved for judgment on the pleadings under Federal Rule of Civil Procedure 12(c), asserting that federal law preempted Plaintiffs' state law tort claims in light of the Supreme Court's decisions in PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011) and Mutual Pharmaceutical Co. v. Bartlett, 133 S. Ct. 2466 (2013). The Generic Defendants alternatively argued that the claims were inadequately pleaded. The parties briefed the motion last fall, and then submitted supplemental briefing this past summer to address the Supreme Court's Bartlett decision.

In an August 14, 2013 Opinion, this Court concluded that Plaintiffs' design defect and failure to warn claims are preempted by federal law, with the exception of the theory that the Generic Defendants failed to timely update their alendronate sodium labels after Merck updated its Fosamax label in March

2010. In re Fosamax Prods. Liab. Litig., --- F. Supp. 2d ----, 2013 WL 4306434, at \*3-7 (S.D.N.Y. 2013). As to that theory, the Court ruled that "plaintiffs have adequately pleaded that some Generic Defendants' delay in updating their labels was unreasonable." Id. at \*3.

The Generic Defendants then sought to move for a more definite statement under Rule 12(e). To resolve a dispute among the parties about the timing and propriety of the contemplated motion, this Court issued a one-page Order on August 29, 2013, which stated in pertinent part:

The PSC correctly points out that Federal Rule of Civil Procedure 12(g)(2) precludes the Generic Defendants from making a Rule 12 motion that was available to them at the time they made their motion under Rule 12(c). Generic Defendants have represented, however, that the motion was not available to them at the time of their Rule 12(c) motion. Without resolving the issue of whether a motion for a more definite statement of fact is barred under Rule 12(g)(2), and noting that it may in fact have merit, the Court will give Generic Defendants the benefit of the doubt and would entertain a timely Rule 12(e) motion.

(ECF No. 1464.)

Teva Pharmaceuticals has now filed the instant Rule 12(e) motion. Teva states that the complaints in the five cases at issue do not assert any allegations against it for failure to update its alendronate sodium label following the FDA's approval of the Fosamax label change. Teva argues that it therefore cannot answer the complaint without prejudicing itself, and that

it should not be forced to answer the preempted (and therefore invalid) claims. Teva also purports to reserve its right to bring a Rule 12(b)(6) motion. (Teva Br. at 2-3 n.2.)

Plaintiffs oppose the motion on two grounds. First, they assert that Teva has waived its opportunity to file a Rule 12(e) motion by not making the motion sooner. Second, Plaintiffs argue that even if the motion is properly before the Court, it should fail as a substantive matter because the complaints provide sufficient detail about Plaintiffs' failure-to-update claims.

## **II. Discussion**

### **A. Legal Standard**

A party may move under Rule 12(e) "for a more definite statement of a pleading to which a responsive pleading is allowed but which is so vague or ambiguous that the party cannot reasonably prepare a response." Fed. R. Civ. P. 12(e). The movant must "point out the defects complained of and the details desired." Id. As a general matter, Rule 12(e) motions are disfavored because they can be used as a tool for delay. See, e.g., In re European Rail Pass Antitrust Litig., 166 F. Supp. 2d 836, 844 (S.D.N.Y. 2001). But where "the movant shows that there actually is a substantial threshold question that may be dispositive, such as a critical date," a more definite statement may be warranted. 5C Charles A. Wright & Arthur R. Miller,

Federal Practice & Procedure § 1376 at 336 (3d ed. 2004); accord Casanova v. Ulibarri, 595 F.3d 1120, 1125 (10th Cir. 2010) (“[T]he preferable procedure when a specific date could support a dispositive defense motion is to require the plaintiff to provide a more definite statement under Fed. R. Civ. P. 12(e).”).

**B. The Motion Is Properly Brought**

The parties continue to dispute whether Teva has waived its right to seek a more definite statement. Rule 12(g) states that “a party that makes a motion under this rule must not make another motion under this rule raising a defense or objection that was available to the party but omitted from its earlier motion.” Fed. R. Civ. P. 12(g)(2). Thus, the question is whether Teva could have brought its Rule 12(e) motion when it moved with the other Generic Defendants for judgment on the pleadings on September 7, 2012.

Teva contends that it could not have done so because it did not have notice of Plaintiffs’ “failure to timely update” theory at that time. In support of this position, Teva notes that the complaints do not explicitly accuse it of any failure to update its alendronate sodium label. In a letter to the Court which preceded the instant briefing, counsel for Teva stated that “[t]his theory was raised in these matters for the first time in Plaintiffs’ opposition” to the prior Rule 12 motion. (Bogle Dec.

Ex. C.) Teva further urges that it "had no way to anticipate that the Court would recognize a 'failure-to-update' claim or the form in which that claim would be permitted by the Court." (Reply at 1-2.)

The Court concludes that Teva's Rule 12(e) motion was not available to it when the Generic Defendants moved for judgment on the pleadings last September. The "failure to update" theory does not appear in the complaints, and Plaintiff's counsel acknowledged at oral argument that its first appearance in this MDL was in Plaintiffs' previous opposition brief. (Oral Arg. Tr. at 9.) Moreover, that motion was filed prior to the Supreme Court's Bartlett decision, which clarified the issues before this Court. Teva therefore had no cause to bring a motion for a more definitive statement when it and the other Generic Defendants made their Rule 12(c) motion.

Plaintiffs argue that after they mentioned "failure to update" in their opposition to the Rule 12(c) motion, Teva should have attempted to seek a more definite statement, either in reply or as part of the post-Bartlett supplemental briefing. Plaintiffs thus contend that Teva missed its chance to move under Rule 12(e). This argument is not compelling. As a preliminary matter, the Court is not convinced that Teva could have properly raised a Rule 12(e) motion for the first time in its reply papers or supplemental briefing. Cf. Estate of Rick ex

rel. Rick v. Stevens, No. C 00-4144, 2001 WL 34008709, at \*5-7 (N.D. Iowa July 18, 2001) (concluding that defendants waived a Rule 12(b)(3) challenge even after including it in the reply briefing for their motion on other Rule 12 grounds, because it was omitted from the original motion). See generally Cuba-Diaz v. Town of Windham, 274 F. Supp. 2d 221, 230 n.8 (D. Conn. 2003) (noting established Second Circuit precedent that "new arguments may not be made in a reply brief").

Even if Teva could have done so, however, Plaintiffs' argument still fails because Rule 12 is plain on its face. It precludes Teva from making a second Rule 12 motion only where the objection was available but "omitted from its earlier motion." Fed. R. Civ. P. 12(g) (emphasis added). Here, Plaintiffs urge that a Rule 12(e) motion became available to Teva after Plaintiffs served their opposition to Teva's 12(c) motion. But by its very terms, Rule 12(g) does not bar an objection that first became available after the earlier motion was served. To avoid the plain language of the rule, Plaintiffs cite a Ninth Circuit case which states that "certain defenses under Fed. R. Civ. P. 12 must be raised at the first available opportunity or, if they are not, they are forever waived." Am. Ass'n of Naturopathic Physicians v. Hayhurst, 227 F.3d 1104, 1106 (9th Cir. 2000). The Court declines to adopt Plaintiffs'

interpretation of this passage, because it does not comport with the plain language of Rule 12.

Plaintiffs also make much of the fact that over a year passed between their brief raising a failure-to-update argument and the instant motion. (Oral Arg. Tr. at 13; Pl. Opp. at 6 (stating that "Teva sat idly by for more than a year").) This is hardly significant, given that much of the delay was a consequence of the parties' joint request to adjourn argument on the earlier Rule 12 motions until after the Supreme Court decided Bartlett. (ECF No. 1248.) Plaintiffs' counsel additionally warns that allowing Teva's motion to proceed would run counter to the efficiency goals of Rule 12 and would render Rule 12(g)(2) a "dead letter." (Oral Arg. Tr. at 13-14.) In light of this Court's ruling that Rule 12(g)(2) does not apply, counsel's warning is moot. The Court nevertheless notes that as a practical matter, nothing in this Opinion is likely to delay the resolution of these cases.

On a fundamental level, everyone involved recognizes that the instant cases are on different footing now than they were before Mensing and Bartlett. This Court's earlier ruling gave Plaintiffs the benefit of liberally reading their complaints to include the failure-to-update theory of liability, even though that theory does not appear therein. See In re Fosamax Prods. Liab. Litig., 2013 WL 4306434, at \*3. This benefit, the Court

observes, is not one that other plaintiffs in litigation against generic drug manufacturers always enjoy. See, e.g., Bowman v. Wyeth, LLC, No. 10 Civ. 1946, 2012 WL 684116, at \*7 (D. Minn. Mar. 2, 2012) (declining to address the failure-to-update theory because plaintiff did not explicitly assert it in his complaint, and dismissing the entire case after Mensing). The Court will not deny Teva the comparatively minor benefit of making a motion regarding Plaintiffs' theory, because Rule 12 does not compel such a result.

### **C. The Merits of the Motion**

The parties also dispute whether a more definite statement is necessary in these cases. Teva argues that if it is made to answer the current complaints, it "will be forced to respond to general failure-to-warn allegations already found preempted." (Teva Br. at 4.) Teva seeks details about Plaintiffs' failure-to-update claims, "which would establish an intelligible theory of liability and would allow Teva to reasonably prepare a response." (Id. at 5.) Plaintiffs respond that the complaints are sufficient to put Teva on notice of "the general nature of claims against it," and that further information is more appropriately obtained through discovery. (Pl. Opp. at 8.)

Contrary to Teva's protests, it need not respond to any theories of liability that have been precluded. Nor will the Court require Plaintiffs to augment their remaining failure-to-

update theory with a burdensome level of detail at this stage. However, Plaintiffs must amend their pleadings to clarify when they took Teva's alendronate sodium. See Strayhorn v. Wyeth Pharm., Inc., --- F.3d ----, 2013 WL 6224337, at \*17-19 (6th Cir. 2013) (concluding that a complaint alleging failure-to-update must include when plaintiffs took the generic drug).

The particulars of these cases demonstrate why this minor amendment is appropriate. The gap between when Merck updated its Fosamax label in March 2010 and when Teva updated its own alendronate sodium label update was, according to Teva, three months at most. (Oral Arg Tr. at 16.) Plaintiffs have not endorsed Teva's timeline, (Nov. 25, 2013 Bogle Letter), but agree that the relevant period is one of "several months" in 2010. (Oral Arg. Tr. at 10-11.) It follows that only those Plaintiffs who took Teva's alendronate sodium during that window in 2010 can possibly allege a valid failure-to-update claim. Teva has thus successfully shown that the period of ingestion by each plaintiff constitutes "a substantial threshold question that may be dispositive." Wright & Miller, § 1376 at 336.

Under these circumstances, requiring Plaintiffs to plead when they took Teva's alendronate sodium does not impose an unreasonable burden upon them. Nor are Plaintiffs correct that they should be permitted to withhold this information until discovery commences, because "such a factual averment is

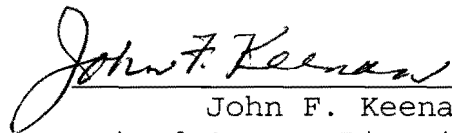
critical to the question of whether the plaintiffs' alleged injuries are in any way connected to the alleged failure to conform" or update the label. Strayhorn, 2013 WL 6224337, at \*19. Plaintiffs are therefore directed to amend their complaints to include this information.

### **III. Conclusion**

For the reasons stated above, Teva's motion for a more definite statement is denied in part. Plaintiffs must, however, amend their pleadings to include one detail: the time frame during which they took Teva's alendronate sodium. Plaintiffs are directed to file their amended pleadings no later than January 31, 2014.

**SO ORDERED.**

Dated: New York, New York  
December *18*, 2013

  
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John F. Keenan  
United States District Judge